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APPLICATION NO. 09/291,227	FILING DATE 04/13/99	FIRST NAMED INVENTOR HAYER	ATTORNEY DOCKET NO. M IAM467PA
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EXAMINER

WANG, S

ART UNIT	PAPER NUMBER
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1617

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DATE MAILED:

09/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/291,227

Applicant(s)

HAYEK, MICHAEL G.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Receipt of applicants' amendments and remarks submitted July 12, 2001 is acknowledged.

Double Patenting Rejection

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-12 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,133,323. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons set forth in the prior office action.

Claim Rejections 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jyonouchi et al. (CA Abstract, AN 1994:321921 of record) in view of Anon (of record), Ito et al. (US Patent 5,993,714) and Krinsky (Medline Abstract, AN 91090021) further in view of CRC Handbook of Toxicology (of record) for reasons set forth in the prior office action.

5. Claims 1-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (US Patent 5,993,714) for reasons set forth in the prior office action.

Response to the amendments and arguments

Applicants' amendments submitted July 12, 2001 are persuasive to overcome the rejection under 35 U.S.C. 112 as set forth in the prior office action.

Applicants' arguments submitted July 12, 2001 have been fully considered, but are not persuasive for reasons discussed below.

Applicants assert that the claimed invention is not obvious over the claims in US Patent 6,133,323 because '323 does not teach expressly the employment of lutein for the particular functions and in the claimed dosage. The examiner disagrees. '323 claims a method for enhancing immune response and improving overall health of companion animal such as dog or cat comprising feeding the animal 1-50 mg/day of β -carotene. '323 further teaches lutein is similarly useful as b-carotene. Therefore, a prima facie case is established. Regarding the particular purpose of the method herein, e.g., increasing lutein concentration in the blood, increasing immunoglobium concentration or increasing lymphocyte cell, note such purpose is not seen to patentably distinguish the claims since the process of the ultimate method, i.e., feeding animal with lutein, is not affected by such purpose.

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Regarding the remarks about animal models, the fact is that lutein has been suggested to be useful for enhancing the immune response in mammals, particularly in humans and has been proved to be useful for the enhancement in mouse. Further, Ito et al. teaches generally that antioxidants, including lutein, are known to be useful in a variety of animals. It would have been reasonably expected to be useful for the enhancement in dog and cat, considering that mouse is genetically closer to dog and cat than to humans.

The remarks that Anon's dietary supplement is associated to *eye* is not probative because any dietary supplement would have reasonably been expected to be associated to the health of the animal as a whole, which including each and every part of the body.

In response to the remarks that Ito et al. does not teach particularly the employment of lutein for the purpose to increase immune response, the examiner reiterates that the ultimate utility (feeding lutein to dog or cat) for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. See the prior office action page 6.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shengjun Wang

AU 1617

September 13, 2001



RUSSEL TRAVERS
PRIMARY EXAMINER
GROUP 1200